# FOOD AND DRUG ADMINISTRATION CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)

Anti-Infective Drugs Advisory Committee Meeting Hilton Washington, DC/Gaithersburg December 9, 2009

## **Meeting Roster**

### ANTI-INFECTIVE DRUGS ADVISORY COMMITTEE MEMBERS (Voting)

W. Kemper Alston, M.D., M.P.H.

Professor of Medicine, Infectious Diseases Unit Fletcher Allen Health Care University of Vermont College of Medicine Burlington, VT

Dean Follmann, Ph.D.

Assistant Director for Biostatistics Chief Biostatistics Research Branch National Institute of Allergy and Infectious Diseases/National Institutes of Health Bethesda, MD

Matthew Bidwell Goetz, M.D.

Professor of Clinical Medicine David Geffen School of Medicine at UCLA Chief, Infectious Diseases Section VA Greater Los Angeles Healthcare System Los Angeles, CA

Peter Katona, M.D.

Associate Professor of Clinical Medicine David Geffen School of Medicine at UCLA Los Angeles, CA

**INDUSTRY REPRESENTATIVE (Non-Voting)** 

John H. Rex, M.D., F.A.C.P. Infection Clinical Vice President AstraZeneca; Alderley House United Kingdom Susan Rehm, M.D.

Vice Chair, Department of Infectious Disease Cleveland Clinic Cleveland, OH

Kent A. Sepkowitz, M.D.

Vice Chairman, Clinical Affairs Director, Hospital Infection Control Memorial Sloan-Kettering Cancer Center New York, NY

Melvin P. Weinstein, M.D.

New Brunswick, NJ

Professor of Medicine and Pathology Chief, Division of Infectious Diseases, Allergy & Immunology Robert Wood Johnson Medical School Director, Microbiology Laboratory Robert Wood Johnson University Hospital

John G. Bartlett, M.D.Assistant DirectionProfessor of MedicineProvidence PopularJohns Hopkins UniversityPortland, ORBaltimore, MD

TEMPORARY ANTI-INFECTIVE DRUGS ADVISORY COMMITTEE MEMBERS (Voting)

William J. Calhoun, M.D. Vice Chair for Research

Department of Internal Medicine University of Texas Medical Branch Galveston, TX

Thomas R. Fleming, Ph.D. Professor of Biostatistics

University of Washington

Seattle, WA

James E. Leggett, M.D.
Associate Professor, Medicine
Oregon Health & Science University

Assistant Director, Medical Education Providence Portland Medical Center

<u>Ken Makowka</u> (Patient Representative) Wilton, CT

Thomas Moore, M.D., F.A.C.P. (Acting Chair) Clinical Professor, Department of Medicine University of Kansas School of Medicine Wichita, KS

Donald Poretz, M.D.

Clinical Professor of Medicine

Georgetown University School of Medicine & Virginia Commonwealth University

Annandale, VA

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### L. Barth Reller, M.D., D.T.M.&H.

Professor of Medicine and Pathology Director of Clinical Microbiology Duke University Medical Center Durham, NC

Yu Shyr, Ph.D.

Professor and Chief Division of Cancer Biostatistics Vanderbilt University School of Medicine Nashville, TN

### **GUEST SPEAKER (Non-Voting)**

Nancy Kline Leidy, Ph.D Senior Vice President, Scientific Affairs United BioSource Corporation Bethesda, MD

### FDA PARTICIPANTS (Non-Voting)

Edward Cox, M.D., M.P.H.
Director
Office of Antimicrobial Products

Katherine Laessig, M.D.
Deputy Director
Division of Anti-Infective and
Ophthalmology Products
Office of Antimicrobial Products

Sumati Nambiar, M.D., M.P.H.
Deputy Director for Safety
Division of Anti-Infective and
Ophthalmology Products
Office of Antimicrobial Products

James M. Steckelberg, M.D.
Professor of Medicine
Mayo Clinic College of Medicine
Rochester, MN

<u>Kathleen Young</u> (Acting Consumer Representative) Executive Director Alliance for Prudent Use of Antibiotics Boston, MA

Joe Toerner, M.D., M.P.H.
Associate Director for Medical Affairs
Office of Antimicrobial Products

Mary Singer, M.D., Ph.D.
Acting Medical Team Leader
Division of Anti-Viral Drug Products
Office of Antimicrobial Products

Thamban Valappil, Ph.D. Statistical Team Leader Division of Biometrics IV Office of Biostatistics